

CLAIMS

1. A rapidly disintegrating oral controlled release pharmaceutical composition comprising at least one active ingredient, and a polymer system comprising of at least two polymers wherein one is an acid insoluble polymer and the other is a bioadhesive polymer, which retard the release of the active ingredient in the stomach while providing rapid release of the said active ingredient in the pH above 5.5, optionally with other pharmaceutically acceptable excipients.
2. A composition according to claim 1, wherein said active ingredient is selected from a group comprising antibiotics, such as cephalosporins and penicillins, and their pharmaceutically acceptable salts, hydrates, polymorphs, esters, and derivatives thereof.
3. A composition according to claim 1, wherein said active ingredient is amoxicillin trihydrate.
4. A composition according to claim 1, wherein said active ingredient is cephalexin, or its pharmaceutically acceptable salts, hydrates, polymorphs, esters, and derivatives thereof.
5. A composition according to claim 1, which comprises at least two active ingredients selected from the group comprising amoxicillin, ampicillin, cloxacillin, clavulanic acid, cephalosporins, or pharmaceutically acceptable salts or derivatives thereof.
6. A composition according to claim 1, wherein the polymer system comprises of polymers selected from a group comprising polyvinyl pyrrolidone, polyvinyl acetate, methacrylic acid polymers, acrylic acid polymers, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate phthalate, cellulose acetate butyrate, cellulose acetate propionate, and alginates, cellulose derivative, polyethylene oxide, chitosans, and polycarbophil, or mixtures thereof.
7. A composition according to claim 1, wherein the acid insoluble polymer is selected from a group comprising methacrylic acid polymers, acrylic acid

polymers, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate phthalate, cellulose acetate butyrate, cellulose acetate propionate, and alginates, or mixtures thereof.

8. A composition according to claim 1, wherein the bioadhesive polymer is selected
5 from a group comprising polycarbophil such as Noveon® AA1, and chitosans.
9. A composition according to claim 6, wherein the polymer system comprises
methacrylic acid polymer and polycarbophil.
10. A composition according to claim 9, wherein the methacrylic acid polymer is
selected from a group comprising Eudragit® L-100, Eudragit® RS, and
10 Eudragit® LS.
11. A composition according to claims 1-10, which additionally comprises a
cellulose derivative.
12. A composition according to claim 11, wherein the cellulose derivative is selected
from a group comprising alkyl cellulose such as ethylcellulose and carboxyalkyl
15 cellulose.
13. A composition according to claim 12, wherein the cellulose derivative is alkyl
cellulose such as ethylcellulose.
14. A composition according to claims 9 to 13, wherein the ratio of methacrylic acid
polymer and polycarbophil is 10:1 to 1:10 by weight of the composition.
- 20 15. A composition according to claim 1, wherein the pharmaceutically acceptable
excipients are selected from the group comprising diluents disintegrants, binders,
fillers, bulking agent, coating agents, plasticizers, organic solvents, colourants,
stabilizers, preservatives, lubricants, glidants, chelating agents, and the like.
16. A composition according to claims 1-15, which is formulated as tablets or
25 capsules.
17. A process for preparation of a composition according to claim 1 which comprises
of the following steps:

- i) mixing of active ingredient(s) and polymer(s),
- ii) optionally adding one or more other pharmaceutically acceptable excipients, and
- iii) formulation of the mixture into a suitable dosage form.

5 18. A process according to claim 17, wherein said active ingredient is selected from a group comprising antibiotics, such as cephalosporins and penicillins, and their pharmaceutically acceptable salts, hydrates, polymorphs, esters, and derivatives thereof.

10 19. A process according to claim 17, wherein said active ingredient is amoxicillin trihydrate.

20. A process according to claim 17, wherein said active ingredient is cephalexin, or its pharmaceutically acceptable salts, hydrates, polymorphs, esters, and derivatives thereof.

15 21. A process according to claim 17, which comprises at least two active ingredients selected from the group comprising amoxicillin, ampicillin, cloxacillin, clavulonic acid, and cephalosporins, or pharmaceutically acceptable salts or derivatives thereof.

20 22. A process according to claim 17, wherein the polymer system comprises of polymers selected from a group comprising polyvinyl pyrrolidone, polyvinyl acetate, methacrylic acid polymers, acrylic acid polymers, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate phthalate, cellulose acetate butyrate, cellulose acetate propionate, and alginates, cellulose derivative, polyethylene oxide, chitosans, and polycarbophil, or mixtures thereof.

25 23. A process according to claim 17, wherein the acid insoluble polymer is selected from a group comprising methacrylic acid polymers, acrylic acid polymers, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate phthalate, cellulose acetate butyrate, cellulose acetate propionate, and alginates, or mixtures thereof.

24. A process according to claim 17, wherein bioadhesive polymer is selected from a group comprising polycarbophil such as Noveon® AA1, and chitosans.
25. A process according to claim 22, wherein the polymer system comprises methacrylic acid polymer and polycarbophil.
- 5 26. A process according to claim 25, wherein the methacrylic acid polymer is selected from a group comprising Eudragit® L-100, Eudragit® RS, and Eudragit® LS.
27. A process according to claims 17-26, wherein the composition additionally comprises a cellulose derivative.
- 10 28. A process according to claim 27, wherein the cellulose derivative is selected from a group comprising alkyl cellulose such as ethylcellulose and carboxyalkyl cellulose.
29. A process according to claim 28, wherein the cellulose derivative is alkyl cellulose such as ethylcellulose.
- 15 30. A process according to claims 25-29, wherein the ratio of methacrylic acid polymer and polycarbophil is 10:1 to 1:10 by weight of the composition.
31. The pharmaceutical composition substantially as herein described and illustrated by the examples.
32. The process for the preparation of a pharmaceutical composition substantially as herein described and illustrated by the examples.
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